

### AMENDMENTS TO THE CLAIMS

1. (Currently amended) A process for amplifying TALL-104 lymphocytes in a homogeneous system within a multi-chamber stack, single fermentation unit comprising:  
adding into the multi-chamber stack an inoculum of at least  $0.7 \times 10^6$  cells/ml in an initial volume of 1/10 to 1/6 of the multi-chamber stack final volume;  
amplifying the cell number by adding a volume of complete medium corresponding to that contained in the multi-chamber stack; and  
recovering at least  $1 \times 10^9$  cells grown in homogeneous conditions.  
the expansions of TALL lymphocytes, wherein at least  $1 \times 10^9$  cells are grown in homogeneous conditions in a single fermentation unit.
2. (Canceled)
3. (Canceled)
4. (Canceled)
5. (Currently amended) The process as claimed in claim 13, wherein said process for amplifying TALL-104 lymphocytes ~~the expansion in the homogeneous system~~ is preceded by a process of pre-expansion in a flask until obtaining a number of cells in an amount comprised from 0.7 to  $1 \times 10^8$ .
6. (Currently amended) The process as claimed in claim 15, wherein the cellular density of the inoculum is at least  ~~$0.7 \times 10^6$  cells/ml and is preferably equal to~~  $0.75 \times 10^6$  cells/ml and, at the harvest time, the density is lower than  ~~$2 \times 10^6$  cells/ml, preferably than~~  $1 \times 10^6$ .
7. (Currently amended) The process as claimed in claim 1[[4]], wherein the multi-chamber stack Cell-Factory<sup>TM</sup> is a 10-chamber unit.
8. (Currently amended) The process as claimed in claim 1, wherein said TALL-104 lymphocytes are selected from the group consisting of: TALL-104, TALL-107, TALL-103/2 cell lines, optionally genetically modified.
9. (Canceled)
10. (Currently amended) The process as claimed in Claim 1, wherein the complete culture medium in the multi-chamber stack cell-factory amplification phase also comprises 10% maximum human serum, ~~preferably in the range of 4 to 6%, still more preferably of 5%, and~~ interleukin in a concentration comprised from 80 to 120 IU/ml.

11. **(Currently amended)** The process as claimed in claim 10, wherein interleukin-2 is added to the cell culture every 48-90 hrs.

12. **(Currently amended)** The process as claimed in claim 10, wherein the cell amplification growth in the homogeneous system takes place in an antibiotic-free culture medium.

13. **(Currently amended)** A process for the preparation of frozen bags of TALL-104 lymphocytes in an amount of at least  $1 \times 10^9$  cells, wherein ~~comprising~~ using the process according to Claim 1 is used.

14. **(Previously presented)** The process as claimed in claim 13, wherein the bag is sealed transversally to a the bag filling collet at least in two points to create at least a sampling chamber containing a cell culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.

15. **(Currently amended)** A process for the preparation of a therapeutic dose of at least  $1 \times 10^9$  TALL-104 lymphocytes in a homogeneous culture comprising using the process according to Claim 1.

16. **(Canceled)**

17. **(Withdrawn, currently amended)** TALL-104 lymphocytes obtainable according to the process of Claim 1 wherein said lymphocytes are characterised by a  $CD3^+$  and  $CD8^+$  immunologic markers expression of 98% min, preferably  $\geq 99\%$ , and by the  $CD56^+$  marker expression of 95% at least, preferably  $\geq 97\%$ .

18. **(Withdrawn, currently amended)** TALL-104 lymphocytes according to claim 17 characterised by a biological activity, determined by a cytotoxicity assay on appropriate target cells, equal to at least 70% of the control.

19.-24. **(Canceled)**

25. **(New)** The process as claimed in claim 10 wherein said complete culture medium comprises 4-6% human serum.

26. **(New)** A process according to claim 10, wherein said TALL-104 lymphocytes are genetically modified.

27. **(New)** The process as claimed in claim 26, wherein the bag is sealed transversally to a bag filling collet at least in two points to create at least a sampling chamber containing a cell

**Application No.:** 10/530,108  
**Filing Date:** April 1, 2005

culture volume ranging from 0.1 to 1 ml, physically separated from the culture contained in the bag to perform quality controls.

28. (New) The process of claim 15, wherein the complete culture medium in the cell-factory amplification phase also comprises 10% maximum human serum and interleukin in a concentration from 80 to 120 IU/ml.